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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,716	01/23/2006	Yoshiyuki Ishikura	47237-5022-00 (412785)	9548

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EXAMINER	
VAKILI, ZOHREH	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,716	ISHIKURA ET AL.	
	Examiner	Art Unit	
	ZOHREH VAKILI	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-46* is/are pending in the application.

4a) Of the above claim(s) *32-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-31 and 39-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Claims 17-46 are presented for examination.

Applicant's Amendment filed September 28, 2009 has been received and entered into the present application. Applicant has amended claims 32-38 which are now drawn to method of preparing. Claims 32-38 are **withdrawn** pursuant to 37 C.F.R. 1.142(b) as being drawn to non-elected subject matter. Applicant had elected Group III drawn to a method of ameliorating liver diseases comprising administering an omega-9 unsaturated fatty acid. The claims corresponding to the elected subject matter are claims 17-31 and 39-46 and such claims are herein acted on the merits.

Applicant's arguments, filed September 28, 2009 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Applicant's certified priority documents submitted 01/23/2006 has been received and entered into the present application.

Drawings as filed 01/23/2006 has been received and entered.

IDS filed 01/23/2006, 03/26/2007, and 02/4/2009 was acknowledged in the previous Office action dated 04/01/2009.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what Applicant is referring to, the term "The method of an omega-9 unsaturated fatty acid or a compound having an omega-9 unsaturated fatty acid" is vague and unclear.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-31 and 39-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bistrian et al. (US Pat. No. 5320846) and Akimoto et al. (US Pub. No. 2004/0171127 A1.

Bistrian et al. teach a method of treating patients with clinical disorder such as liver, the dysfunction being characterized by depletion of metabolic energy sources. The treatment involves the step of administration of a total enteral nutritional diet, or as a dietary supplement. The invention includes a total enteral nutrition diet having nutritionally acceptable amounts of a lipid source, a protein source, and a carbohydrate source, (see abstract). The patient may suffer from **cancer**, a clinical liver dysfunction or trauma such as ischemia, trauma, sepsis, malnutrition, liver surgery, **hepatitis**, or liver transplant (see col. 4, lines 27-33). In that instance, the diet would consist essentially of a lipid source, a protein source, a vitamin source, a carbohydrate source, and a mineral source. Lipid sources could be from vegetable oil, fish oil or combinations that at least provide adequate amounts of essential fatty acids, e.g., linoleic or alpha linolenic acids, as well as other omega-3 or omega-9 fats (see col. 4, lines 54-62).

Akimoto et al. teach a method for preparing fat comprising a **triglyceride** having a medium chain fatty acid bonded to the 1 and 3 position and a highly unsaturated fatty acid bonded in the 2 position comprises treating a medium chain fatty acid derivative.

The lipase specifically acts on the 1 and 3-position ester bonds and the starting material fat comprises at least one omega-6 18C or more fatty acid containing at least 3 double bonds and/or **omega-9** 18C or more fatty acid containing at least 2 double bonds and no omega-3 highly unsaturated fatty acids. As a fat for use in **foods** and pharmaceuticals for treating and preventing arteriosclerosis, thrombosis and **cancer**, obtained from a Mortierella spp. The omega-9 fatty acid is 6,9-octadecadienoic acid, 8,11-ecosadienoic acid or 5,8,11-ecosatienoic acid and medium chain fatty acid derivative is a 6-12C fatty acid (preferably caprylic or caproic acid) lower alkyl ester (see abstract). The constituent fatty acid contains 45% triglyceride (see paragraph 0017).

It would have been obvious to have combined the teachings of Bistrian et al. and Akimoto et al. to produce a method of preventing or ameliorating liver diseases administering omega-9 unsaturated fatty acid.

In re Kerkhoven (205 USPQ 1069, CCPA 1980) states that "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose: the idea of combining them flows logically from their having been individually taught in the prior."

One of ordinary skill in the art would have been motivated to combine the above references and as combined teach and suggest the invention as claimed. Akimoto et al. teaches the same composition with the same mechanism to be used for the same purpose as the claimed invention. Further, Bistrian et al. teach the same composition to

be useful in treating liver diseases. Finally, one would have a reasonable expectation of success given that the above references provide a detailed blueprint for making the liquid drug preparation, and the steps of which are routine to one of ordinary skill in the art.

Thus the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and was as a whole, *prima facie* obvious.

Response to Argument

Applicants traverse the rejection. First, Bistrian's lipid component does not function to treat liver dysfunctions, because the omega-9 fatty acid is not the active component, but rather adenosine is the active component. Thus, Bistrian is not considered for all that it teaches as a whole. Bistrian teaches a treatment for clinical disorders characterized by depletion of metabolic energy sources. See e.g., Abstract of Bistrian. For example, Bistrian states: The present invention generally relates to providing adenosine, or one of its related nucleosides, in an enteral feeding regimen which enables splanchnic tissues to more rapidly generate ATP, or other related nucleotides, during or following shock or trauma, including post-transplant situations. See Bistrian, col. 3, lines 63-68. Additionally, Bistrian describes the "effective" component of the diet as adenosine. The invention includes a total enteral nutrition diet having nutritionally acceptable amounts of a lipid source, a protein source, a carbohydrate source, a vitamin source, and a mineral source, and an effective amount of adenosine to achieve normal metabolic levels of ATP and/or its precursors in ATP

deficient organs of a recipient host. See also Abstract of Bistrian (emphasis added). Bistrian thus fails to teach or suggest using an omega-9 fatty acid or an omega-9-constituted fat as the active component to ameliorate liver diseases associated with hepatopathy.

Applicant's argument in regard to Bistrian reference is not persuasive. This invention is directed towards a method of ameliorating liver diseases associated with hepatopathy comprising administering an omega-9 unsaturated fatty acid. The word comprising is an open ended language that can include other ingredients in the preparation. Importantly, Bistrian teaches a total enteral nutrition diet having nutritionally acceptable amounts of a lipid source, a protein source, and a carbohydrate source, where the lipid source can be from omega-9 fats. Further, the adenosine may also be administered as a total enteral nutrition diet. In that instance, the diet would consist essentially of a lipid source, a protein source, a vitamin source, a carbohydrate source, and a mineral source. Lipid sources could be from vegetable oil, fish oil or combinations that at least provide adequate amounts of essential fatty acids, e.g., linoleic or alpha linolenic acids, as well as other omega-3 or omega-9 fats (see col. 4, lines 54-62). The patient may suffer from **cancer**, a clinical liver dysfunction or trauma such as ischemia, trauma, sepsis, malnutrition, liver surgery, **hepatitis**, or liver transplant (see col. 4, lines 27-33). Therefore, Applicants remarks are not persuasive where suggesting that Bistrain fails to teach the instant claim invention using omega-9 to treat liver diseases.

Second, Akimoto does not teach liver diseases. Akimoto thus fails to teach or suggest using an omega-9 fatty acid or an omega-9-constituted fat as the active component to ameliorate liver diseases associated with hepatopathy. The Office next asserts that it would have been obvious to combine Bistrian and Akimoto, because "[i]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose." Office Action, page 10 (citing In re Kerkhoven, 626 F.2d 846, 850, 205 U.S.P.Q. 1069, 1072 (C.C.P.A. 1980)). The Office presumably refers to cancer treatment as the same purpose taught by Bistrian and Akimoto. Applicants disagree. The Office mischaracterizes Akimoto and then misapplies Kerkhoven. Akimoto discloses that an omega-3 or omega-6 fatty acid is useful for treating and preventing cancer. See Akimoto, ¶¶ [0004], [0014]. However, Akimoto does not disclose the anti-cancer function of an omega-9 fatty acid. Akimoto in fact discloses that an omega-9 fatty acid may function as an anti-inflammatory, anti-allergic, or anti-rheumatic agent. See Akimoto, ¶ [0015]. Accordingly, Bistrian and Akimoto cannot overlap in their teachings, because Akimoto simply fails to teach the anti-cancer function of an omega-9 acid. The Office's application of Kerkhoven is thus unsupported absent a showing of the "same purpose." The amended claims recite ameliorating liver diseases associated with hepatopathy using an omega-9 fatty acid or a compound having an amega-9 fatty acid as a constituent fatty acid as the active component.

Examiner does not find Applicant's arguments persuasive. According to Akimoto and Applicant's own discussion the Akimoto reference teach omega-9 acid with an anti-inflammatory function and Bistrian teaches the treatment of hepatitis with omega-9 acid

(see col. 4, lines 27-33). Hepatitis is an inflammation of the liver, therefore, to a patient to be treated for hepatitis is in need of an anti-inflammatory drug. Both references are supported for showing the same purpose. Especially, the amended claims recite ameliorating liver diseases associated with hepatopathy using an omega-9 fatty acid or a compound having an amega-9 fatty acid as a constituent fatty acid as the active component.

Applicant's remarks have been fully and carefully considered in their entirety, but fail to be persuasive.

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 9:00-6:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner 1614 December 31, 2009

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614